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EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group V, drawn to Listeria monocytogenes in the Paper filed April 9, 2003 is acknowledged. Applicant appears to, in general, correctly identify the claims that are included in this election. However, as Applicant is aware, claims 1-15 were cancelled by preliminary amendment on October 9, 2001 and are therefore not pending and not included in this election or action.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 6-18,21,22,25-28,31,32,35,36,39,40,43-45,48 and 49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In analysis of the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that "Satisfactory disclosure of a ``representative number'' depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register:

December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.)

All of the current claims encompass a genus of nucleic acids which are defined solely by function, without any structural elements whatsoever. These nucleic acids are not disclosed in the specification. Specifically, claim 16, for example, is drawn to any primers which function to amplify any generic sequence which has simple sequence repeats. This genus, which is literally comprises many hundreds of trillions of different possible sequences, is represented in the specification by only the particularly named SEQ ID Nos. Thus, applicant has express possession of, at most, 42 different sequences which amplify such repeats, in a genus which comprises hundreds of trillions of different possibilities. Here, no common element or attributes of the sequences are disclosed. No structural limitations or requirements which provide guidance on the identification of sequences which meet these functional limitations is provided.

It is noted in the recently decided case The Regents of the University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997) decision by the CAFC that

"A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See Fiers, 984 F.2d at 1169- 71, 25 USPQ2d at 1605- 06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will

hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. "

In the current situation, the definition of the primers, probes and gene chips is precisely the situation of naming a type of material which is generally known to likely exist, but, except for those disclosed, is in the absence of knowledge of the material composition and fails to provide descriptive support for the generic claim to any "sequence-adapted for exponential amplification of a polymorphic simple sequence repeat locus in a genome of a prokaryote", for example.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

"...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

The current situation is a definition of the compound solely but its functional utility, as a primer or probe, without any definition of the particular sequence, the particular chemical structure of the primers which amplify the SSR sequences, or any particular element that is common to primers which amplify SSR sequences.

In the instant application, certain specific SEQ ID NOs are described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

"...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any nucleic acids other than those expressly disclosed. Therefore, the claims fail to meet the written description requirement by encompassing sequences which are not described in the specification.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 6-18,21,22,25-28,31,32,35,36,39,40 are rejected under 35 U.S.C. 102(b) as being anticipated by Rasmussen et al (Microbiology (1995) 141:2053-2061).

Rasmussen teaches a series of PCR primers and probes which amplify SSR regions in *Listeria monocytogenes* (see page 2054, column 2). In particular, the primers which amplify the *iap* gene, a region shown in figure 1 on page 2059, also shows the presence of several TACAAA six mer repeat units, AAA, monomer SSR units as well as on AAAAA monomer repeat unit that is outside the coding region (see type 2 line, last row, figure 1) and one TAATAA trimer repeat and a CACA dimer repeat within the coding region (see figure 1, page 2059). The PCR products formed by Rasmussen will inherently function as allele specific probes and are inherently allele specific oligonucleotides (see page 2054, column 2).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 43-45,48 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rasmussen et al (Microbiology (1995) 141:2053-2061) as applied to claims 6-18,21,22,25-28,31,32,35,36,39,40 above and further in view of Gingeras (U.S. Patent 6,228,575).

Rasmussen teaches a series of PCR primers and probes which amplify SSR regions in *Listeria monocytogenes* for diagnostic purposes (see page 2053, column 2 and page 2054, column 2). In particular, the primers which amplify the iap gene, a region shown in figure 1 on page 2059, also shows the presence of several TACAAA six mer repeat units, AAA, monomer SSR units as well as on AAAAA monomer repeat unit

that is outside the coding region (see type 2 line, last row, figure 1) and one TAATAA trimer repeat and a CACA dimer repeat within the coding region (see figure 1, page 2059). The PCR products formed by Rasmussen will inherently function as allele specific probes and are inherently allele specific oligonucleotides (see page 2054, column 2).

Rasmussen does not teach diagnosis of *Listeria monocytogenes* using DNA chips.

Gingeras teaches a method of detecting *Listeria* by detecting nucleic acids on a DNA chip (see claims 1 and 78 and columns 7 and 8).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use the DNA chip of Gingeras in the detection method of Rasmussen since Gingeras states "This invention provides methods, compositions and devices for identifying the group or species of an organism and obtaining functional phenotypic information about the organism based on genotypic analysis of one or more genomic regions of the organism (see column 7, lines 50-54)." An ordinary practitioner would have been motivated to use the probes and primers of Rasmussen in the Gene chip of Gingeras in order to identify the various types of *Listeria monocytogenes* as expressly motivated by both Rasmussen and Gingeras. The motivation to use a gene chip would arise because Gingeras teaches that this is a simple method to identify and characterize organisms (see column 2, lines 60-62).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is 703-308-6568. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jeffrey Fredman
Primary Examiner
Art Unit 1634

May 15, 2003

Continuation of Disposition of Claims: Claims withdrawn from consideration are 19,20,23,24,29,30,33,34,37,38,41,42,46,47,50 and 51.